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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,698	01/23/2002	Tatsuki Shiota	Q68142	8252

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,698	SHIOTA ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *3-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 7-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *April 23, 2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTIONS

Receipt of applicants' amendments and remarks submitted April 16, 2004 is acknowledged.

Double Patenting Rejections

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-2, 7-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-26 of U.S. Patent No. 6,451,842. Although the conflicting claims are not identical, they are not patentably distinct from each other because '182 claims a method of inhibiting the binding of chemokine to the receptor of target cell by using compounds or their salts that are substantially overlap with the compounds herein employed, and encompasses the elected species. See the claims. Even '182 does not expressly claim the inhibiting of CCR3 or the method or treating CCR3 related disease, the practice of the claims in '183, e.g., administering the compounds to a subject, would have inherently inhibiting CCR3, and preventing disorders associated with CCR3.

Claim Rejections 35 U.S.C. 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2 and 7-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling the composition herein for treating the diseases listed in claim8-11, does not reasonably provide enablement for preventing such diseases, or for treating or preventing other diseases which concerned with CCR3. The claims as amended, are now directed to a method of inhibiting CCR3, and treating and/or preventing a variety disease including AIDS, allergic disease, asthma, allergic rhinitis, inflammatory bowel disease, etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims are directed to a method of preventing various diseases, including allergic diseases, inflammatory diseases, and AIDS. The specification discloses the compositions herein are CCR3 antagonistic and may be useful in alleviating or suppressing the symptoms of the diseases associated with CCR3. However, the specification fails to adequately teach how to use the method to prevent such diseases. Each of the listed diseases may have different etiologies, the specification or the claims does not provide sufficient evidences, or working examples showing the CCR3 antagonist herein would be useful for preventing such diseases. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure.

Claim Rejections35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 2, 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiota et al. (US 6,451,842, or WO 99/25686, IDS).

8. Shiota teaches therapeutical compounds with a general formula essentially identical to the formula (I) herein employed (see, pages 7-20 in WO 99/25686). The general formula encompasses the particular species herein elected. See, particularly the claims, and the compounds disclosed therein. Shiota also disclosed that the compounds are useful for treating and/or preventing various disorders, including asthma, Crohn disease, etc. See, particularly, page 1.

9. Shiota does not teach expressly the particular species herein elected.

1. However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make the compound since the compound are within the general formula and Shiota teaches examples that structurally close to the elected species. See, compounds 243-247. As to the newly disclosed function, i.e., inhibiting CCR3, note the instant claims are directed to effecting a biochemical pathway with an old and well known compounds. The argument that such claims are not directed to the old and well-known ultimate utility (administering the compound to a subject having asthma) for the compounds, are not

probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical functions. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

10. Claims 1, 2 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al (US 6,166,015).

11. Rogers teaches pyrolidine derivative CCR3 antagonist useful for treating asthma. The general formula (I) in Rogers substantially overlap in scope with the general formula herein, particularly, A is 9I) $-N(R^2)C(O)-$ and B is $-C(O)-$ or $-S(O)_n-$. Roger further teaches a method of treating CCR3 associated disorders, such as asthma by administering the compounds to the patients. See, particularly, the abstract, column 2, lines 18 to 55, and the claims.

12. Rogers does not teach expressly to make a pharmaceutical composition comprising the compounds herein disclosed.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the compounds disclosed by Rogers, which are also encompassed by the general formula herein because such compounds are known to be

useful as CCR3 antagonist and are useful for treating CCR3 associated diseases, such as asthma. Note the difference between the compounds of Rogers et al. and those employed herein (as amended) is by one CH2 (n herein in formula I is 0). One having ordinary skill in the art would have been motivated to prepare the instantly claimed compound because such structurally homologous compounds are expected to possess similar properties. It has been held that compounds that are structurally homologous to prior art compounds are prima facie obvious, absent a showing of unexpected results. In re Hass, 60 USPQ 544 (CCPA 1944); In re Henze, 85 USPQ 261 (CCPA 1950).

Response to the Arguments

Applicants' amendments and remarks submitted April 16, 2004 have been fully considered, but are not persuasive with respect to the rejections set forth above.

Applicants argue that the application are enabled for preventing diseases herein listed on the ground that underlying mechanism involved in prevention and treatment of disease are often the same. Applicants further cited Howard et al. J. Med. Chem. 1998, 41, 2184-2193 as evident for preventing AIDS. The examiner disagrees. First, applicants are confusing treatment and cure. Treatment a disorder is often to ameliorate the symptoms, or delay the development of the disorder, without being enable to cure the disorder, particularly for those disorders the etiologies are not well understood. If one can find a mechanism to cure a disorder, the same mechanism may be employed for preventing such disorders. However, at list up to now, there is no established method for curing AIDS. Howard et al. merely listed CCR3 as a target candidate for preventing AIDS, but never proved that an inhibitor of CCR3 can actually prevent AIDS. Absent working examples, applicants merely repeat the expectation Howard et al. proposed. Further, the

claims are directed to preventing a variety of disorders. Absent showing that those disorders actually have the same controlling biological mechanism, one of ordinary skill in the art would have not reasonably expected that a single method would be able to cure or prevent all the disorders.

The arguments with respect to the obvious rejections are moot in view of the new ground of rejections.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information Disclosure Statements

The information disclosure statements filed on April 23, 2002 had been considered and initialed, but inadvertently misplaced in mailing of the last office action. A copy of initialed 1449 is attached herewith. The IDS filed April 16, 2004, which is a duplicate of the IDS filed April 23, 2002, has not been initialed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571)272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang

July 9, 2004

13.